K013360
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Seed

510(k) Summary
Dfiner Urological Catheter
Date Prepared: 5 October 2001

FEB 2 0 2002

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

NeoSeed Technology, L.L.C.
The Presidio-Old Army Headquarters
Building 220, Suite 120
San Francisco, CA 94129

B. Company Contact

Mark Kieras
Director, Regulatory Affairs

C. Device Name

Trade Name:	Dfiner Urological Catheter
Common Name:	Male Urethrographic Catheter
Classification Name:	Urological Catheter and Accessories

D. Predicate Devices

Imager Torque Catheter, K965229
Imager II Torque Catheter, K011965

E. Description of Device

The Dfiner Urological Catheter is a dual lumen flexible co-axial catheter. The main lumen contains a flexable sheath which houses is a solid flexible rod. Attached to the distal end of the rod is an array of wires. The wire bundle can be advanced and deployed in the bladder to assist with anatomical imaging. Contrast material is introduced through the main lumen. The catheter has a rigid "Y" connector at the proximal end that allows the wire bundle/sheath to be deployed/retracted and access to the main lumen.

D. Intended Use

The Dfiner is indicated for catheterization of the male urethra for the introduction of contrast materials.

E. Comparison of Technological Characteristics

The proposed device is substantially equivalent to the legally marketed predicate devices in design, intended use and materials of manufacture.

Mark Kieras

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2002

Mr. Mark Kieras
Director, Regulatory Affairs
NEOSeed Technology, L.L.C.
22 Hill Street
NEWBURYPORT MA 01950

Re: K013360
Trade/Device Name: NeoSeed Dfiner Urological Catheter
Male Urethrographic Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 FGI and KOD
Dated: January 18, 2002
Received: January 22, 2002

Dear Mr. Kieras:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number : K013360

Device Name : Dfiner Urological Catheter

Indications for Use: The Dfiner is indicated for catheterization of the male urethra for the introduction of contrast materials.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013360